SMARTABLATE™ SYSTEM

Remote Control User Manual

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Preface

The SmartAblate™ Remote Control is an accessory for the SmartAblate™ RF Generator. The physical appearance and the user interface of the two devices are almost identical. However, the remote control is not designed to connect to patient cables such as catheter cables and indifferent electrode cables. The SmartAblate™ Remote Control allows remote control of the SmartAblate™ RF Generator from outside the patient area.

The SmartAblate™ Remote Control was designed to ensure simple, intuitive, and user-friendly operation. This accessory features a touch screen for making selections and setting parameters. Critical safety functions are controlled by buttons that are operated independently of the touch screen. A prominent red **Stop** button has priority over all other functions and connected devices, thus immediately stopping RF energy delivery when pressed.

Use of the SmartAblate™ Remote Control requires familiarity with the device and its operation. Before using the remote control, the user should read this user manual and the user manual for the SmartAblate™ RF Generator.

For more information on training options, please contact Biosense Webster.

We will gladly answer any questions that you may have.

Yours truly,

STOCKERT GmbH

1 Indications

See the SmartAblate™ RF Generator User Manual for indications that apply to the SmartAblate™ RF Generator and the SmartAblate™ Remote Control.

2 Warnings

Note: The warnings in this section cover the SmartAblate™ Remote Control specifically. See the SmartAblate™ RF Generator User Manual for additional warnings.

1. Read this user manual carefully before using the SmartAblate™ Remote Control for the first time. Note especially the instructions in Section 3.4, Setup.

2. Always verify that the remote control's visual and acoustic alarms are working before using the remote control (see Section 5.1, Remote Control Startup).

3. When the remote control has been turned off, power continues to be supplied to the remote control through the mains cable. To completely cut off power to the remote control, disconnect the mains cable from the remote control. To allow easy disconnection in the event of severe power failure, make sure that the remote control is located where there is easy access to the mains cable on the back of the remote control.

4. After turning on the remote control, always wait until the automatic self test has been successfully completed and the remote control has been made the Master of the system (see Section 5.3, Assigning the System Master) before starting the first steps of the procedure on the patient (for example, before anesthesia or before creating percutaneous access). Also, if using accessories that connect to the remote control, verify that the connections to those systems are functional prior to starting the first steps of the procedure. Doing this helps to detect problems with the device before the patient is in a phase of the intervention in which interruption could lead to an increased risk to the patient's health.

5. Use only accessories that have been provided by or recommended by the remote control's manufacturer (see Chapter 4, Accessories). The use of other accessories can have a negative effect on the technical specifications. Do not modify accessories. Visually inspect all accessories on a regular basis. Make sure that the connected cables are not damaged.

6. Make sure that the cable to the SmartAblate™ RF Generator is properly connected and that the remote control can be moved easily without disconnecting it from the generator (see Sections 3.4.1, Setting Up the Remote Control and 3.4.3, Circular Plug Connections).

7. Place the remote control on a secure, non-slip surface as described in Section 3.4.1, Setting Up the Remote Control. Make sure that there is enough free space on all sides of the remote control to allow the heat created by the remote control to escape.

8. Other electrical devices can influence the function of the remote control if they are operated at the same time in the immediate vicinity of the remote control.

9. To avoid damage to the connection cables, do not wrap the cables around the remote control or other apparatus. Coiling the connection cables during normal operation of the remote control creates inductive components, which can lead to interruption of the operation of the remote control.

10. Special safety measures with regard to electromagnetic compatibility (EMC) must be taken with electrical medical devices. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the user manual, may cause harmful interference to radio communications. Similarly, portable and mobile communication devices may cause harmful interference to the functioning of the remote control.

11. If error messages repeatedly appear, stop using the remote control and contact Customer Support.

12. To avoid damage to the remote control and its accessories, use only appropriate cleaning agents (see Sections 3.5, Cleaning and Disinfecting the Remote Control and 4.3, Caring for Accessories).

13. To avoid the risk of electric shock, connect the mains cable from the remote control mains socket (see Item 1 in Section 3.2, Controls on the Back of the Remote Control) to a 3-prong outlet that meets the specifications in Section 7.1, Specifications.

14. The remote control may be opened only by persons authorized by the manufacturer. When the remote control is open, parts that have high voltage or are very hot are accessible and can cause injury. If the remote control is opened by an unauthorized person, any claims on the warranty are void. No modification of the remote control is permitted.

15. If fluid penetrates into the remote control, stop using the remote control and contact Customer Support.

16. If there is any doubt about an unintended increase in RF energy or the proper functioning of the remote control's touch screen, **Data Entry Knob** , or foot pedal, or the functioning of the generator during RF delivery, immediately stop the RF energy delivery by pressing the **Stop** button on the remote control or generator, releasing the foot pedal, or pressing the **Stand-by** button on the remote control or generator. If none of these measures stops the RF energy delivery, disconnect the mains cable from the remote control.

17. Take care when using the SmartAblate™ Remote Control and accessories. Although ablation cannot be started from the remote control when it is the system Monitor, ablation is automatically stopped when the **Stop** button is pressed or the foot pedal is released.

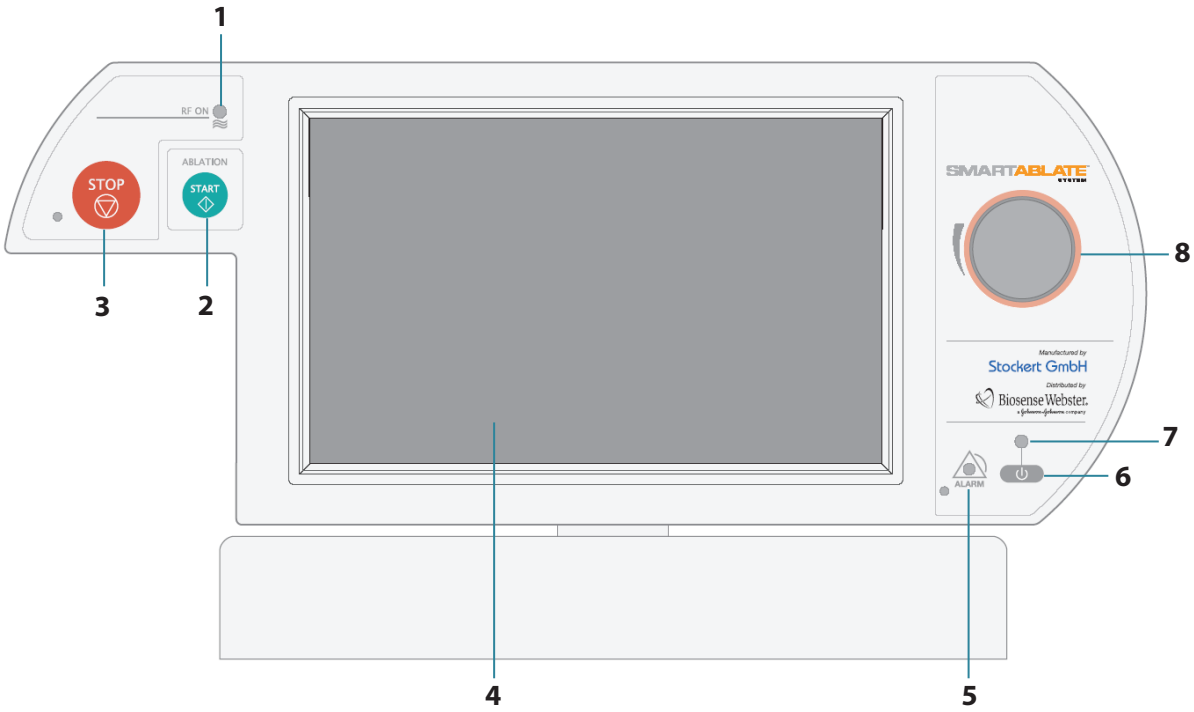
18. The person who connects the remote control and accessories to each other or who uses the remote control and accessories is responsible and liable for installation and operation that complies with IEC/EN 60601-1-1.

19. If several devices are connected to each other, they should be as safe, both individually and together, as specified in IEC/EN 60601-1 and its sub-standards and IEC/EN 60601-1-2.

20. Only classified electrical medical devices may be connected to the remote control. If a PC system does not fulfill the requirements of IEC/EN 60601-1 / UL 60601-1 and their sub-standards, the distance between the PC system and the patient must be at least 1.83 m (6 ft) and the PC system must fulfill the requirements of IEC 950 / UL 60950-1. All medical devices that are connected electrically to the generator must fulfill the requirements of IEC/EN 60601-1-1, the standard for medical systems.

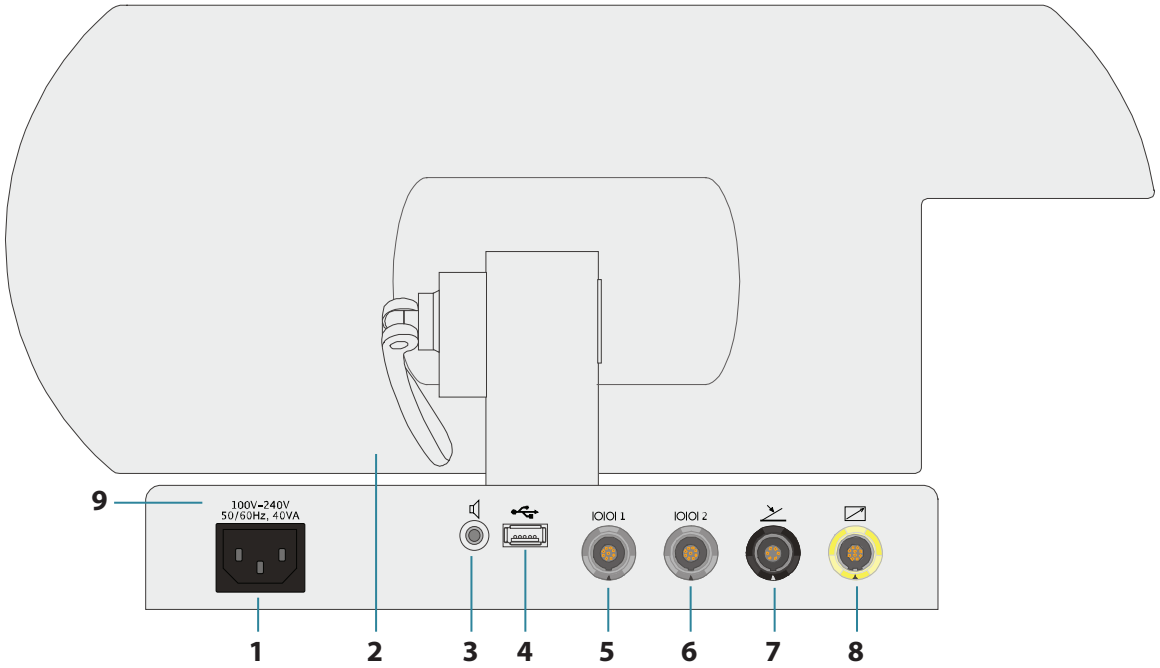
3 Remote Control Overview and Setup

3.1 Controls on the Front of the Remote Control



Item	Description
1	**RF On** indicator
2	**Ablation Start** button
3	**Stop** button
4	Touch screen
5	**Alarm** indicator
6	**Stand-by** button
7	**Stand-by** indicator
8	**Data Entry Knob**

3.2 Controls on the Back of the Remote Control



Item	Description
1	Mains socket and mains rating information
2	Handle for tilting the remote control
3	Speaker receptacle *(not implemented)*
4	USB port (for use by service technicians only)
5	Serial data port 1 – for electrophysiology recording system
6	Serial data port 2 – for CARTO® System
7	Receptacle for SMARTABLATE™ System foot pedal cable
8	Receptacle for SMARTABLATE™ RF Generator cable
9	Device label

3.3 Functional Test and On-Site Training

The SMARTABLATE™ Remote Control is a medical device. In some countries, in order to comply with local regulations, the remote control may not be put into service until the distributor has subjected the remote control to a functional test on site and has trained the person responsible for operating the device in the handling of the remote control per this user manual. All applicable requirements of local regulations must be followed.

3.4 Setup

3.4.1 Setting Up the Remote Control

The SmartAblate™ Remote Control may be used only in medical rooms (IEC/EN 60601-1-1, AAA, 1.201).

Place the remote control on a secure, non-slip surface. If the remote control is placed on a mounting plate, make sure that it is securely fastened.

Do not place the remote control directly above another device.

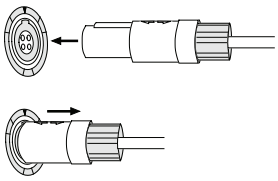
Make sure that there is enough free space on all sides of the remote control to allow the heat created by the remote control to escape.

Make sure that the cable to the SmartAblate™ RF Generator is properly connected (see Section 3.4.3, Circular Plug Connections) and the remote control can be moved easily without disconnecting it from the generator. If the cable to the generator is disconnected when the remote control is the system Master, ablation is automatically stopped.

3.4.2 Mains Connection

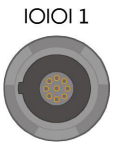
The SmartAblate™ Remote Control automatically adjusts for the necessary mains voltage and frequency. To avoid the risk of electric shock, connect the mains cable from the remote control mains socket (see Item 1 in Section 3.2, Controls on the Back of the Remote Control) to a 3-prong outlet that meets the specifications in Section 7.1, Specifications. Use only the mains cable supplied by the manufacturer or distributor for the country where the remote control is being used.

3.4.3 Circular Plug Connections



The circular plugs on the accessory cables are the same color as the receptacles on the back of the remote control (see Section 3.2, Controls on the Back of the Remote Control). To connect an accessory cable to the remote control, align the arrow on the plug with the mark on the receptacle and push in without unnecessary force until a click indicates that the connector is locked in the receptacle. If the plug does not fit in the receptacle, verify that the color coding matches and that the number of pins in the plug is appropriate for the receptacle. To remove the plug, gently pull back the sleeve on the plug and pull the plug out of the receptacle.

3.4.4 Serial Data Connections



Devices that exchange data with the generator, such as the Carto® 3 System, the Carto® XP System, electrophysiology recording systems, and other external compatible monitoring systems can be connected to the serial data ports on the back of the remote control (see Items 5 and 6 in Section 3.2, Controls on the Back of the Remote Control). These connections can be tested following instructions available in the SmartAblate™ RF Generator User Manual.

3.4.5 Tilting the Remote Control

The upper portion of the remote control can be tilted for easier viewing. Hold the top or side of the remote control while you release the handle behind it. Tilt the remote control to the desired angle and then push the handle back into place. Verify that the handle is completely closed and that the remote control is locked in place before you release your hold of the remote control.

3.4.6 Connection to the SmartAblate™ RF Generator

Plug the connection cable from the SmartAblate™ RF Generator into the receptacle for the generator cable (see Item 8 in Section 3.2, Controls on the Back of the Remote Control) as described in Section 3.4.3, Circular Plug Connections.

3.5 Cleaning and Disinfecting the Remote Control

WARNINGS

- The SmartAblate™ Remote Control must be turned off and the mains cable must be disconnected from the remote control before cleaning and disinfecting the remote control.
- The SmartAblate™ Remote Control and mains cable must not be sterilized.

Use a dry microfiber cloth to clean the remote control's touch screen. If damp cleaning is necessary, moisten a soft cotton or linen cloth with commercial glass cleaner that does not contain alcohol and wipe the screen. Do not spray the cleaner directly onto the screen.

Use a soft, damp, lint-free cloth to clean and disinfect the housing of the remote control. Use only non-flammable and non-explosive substances. Water or soapy water is recommended for cleaning. Make sure that no liquid penetrates the inside of the remote control.

The following disinfectants may be used for disinfecting the remote control and its cables:

- Lysoformin® spezial
- Kodan®
- Meliseptol®
- Commercial disinfectants that do not contain ethyl alcohol

Caution: The following substances must not be used: acetone, benzene, acids of any kind (including acetic acid and citric acid), scouring agents, nitro dilutions and other organic solvents. Do not use any agent containing ethyl alcohol to clean the remote control. Iodine or disinfectants containing dyes cause discoloration of the housing and should not be used. Perform disinfection by wiping, not by spraying. Avoid condensation. If cleaning or disinfecting the remote control

with flammable or explosive substances cannot be avoided, make sure these substances have completely evaporated before the remote control is turned on.

3.6 Protecting Against Damage

In addition to being operated and maintained per the instructions in this user manual, the SmartAblate™ Remote Control must also be protected against damage. This includes installing the remote control in a safe location and protecting the remote control against moisture, contamination, and contact with flammable or explosive substances.

Make sure that all cables to devices and accessories are arranged in a way that prevents tripping. Make sure that the cable to the SmartAblate™ RF Generator is properly connected (see Section 3.4.3, Circular Plug Connections) and that the remote control can be moved easily without disconnecting it from the generator.

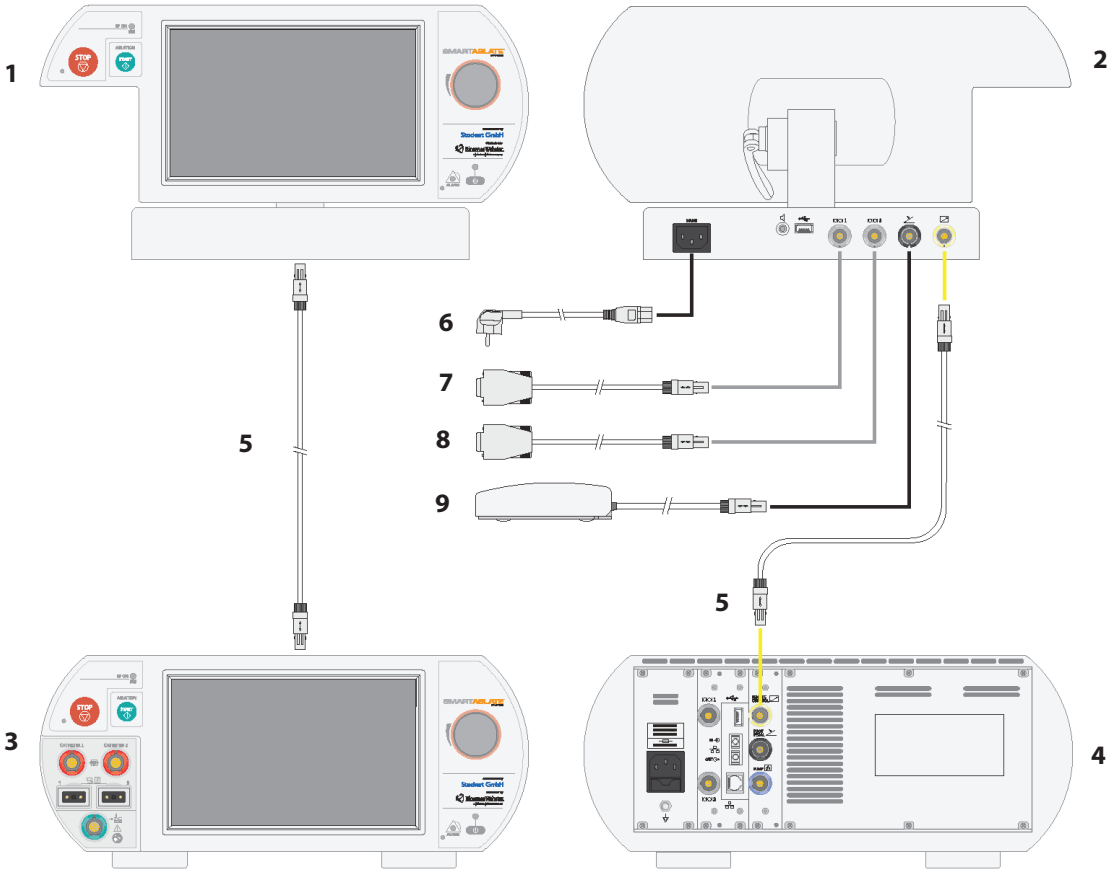
Always carry the remote control with two hands. To transport the remote control over long distances or to send the remote control for service, use the original packaging. If the original packaging is not available, contact the manufacturer or distributor for a replacement.

3.7 Disposal

Inadequately treated electronic waste poses environmental and health risks. Follow local regulations for disposal of the SmartAblate™ Remote Control and its electrical or electronic accessories. To ensure proper disposal, there is also the option of contacting your Biosense Webster representative regarding return of the remote control and its accessories.

4 Accessories

4.1 Diagram of the Remote Control and Accessories



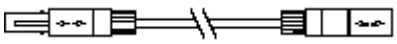
Item	Description
1	Front of SmartAblate™ Remote Control
2	Back of SmartAblate™ Remote Control
3	Front of SmartAblate™ RF Generator
4	Back of SmartAblate™ RF Generator
5	Connection cable to SmartAblate™ RF Generator
6	Mains cable
7	Serial data communication cable for electrophysiology recording system
8	Serial data communication cable for Carto® System
9	Foot pedal

4.2 Accessory Lists

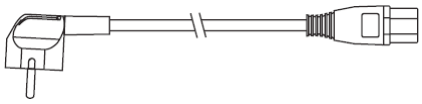
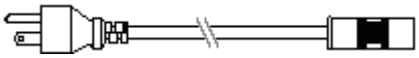
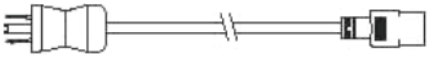
The following is a list of accessories for the SmartAblate™ Remote Control.

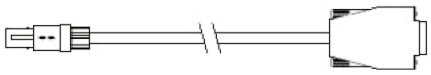
⚠ WARNING
Use only the original accessories provided by or recommended by the manufacturer for the SmartAblate™ Remote Control. If you use accessories that are not authorized by the manufacturer, the safety of the device and system is not guaranteed.

4.2.1 Foot Pedal

Item	Part #	
Foot Pedal, length of connection cable: 3 m		
Worldwide, except China	M490005	
China	M4900405	
Foot Pedal Extension Cable, length: 7 m (Redel-6 → Redel-6, black)	M490026	

4.2.2 SmartAblate™ Cables

Item	Part #	
Connection Cable from SmartAblate™ RF Generator to SmartAblate™ Remote Control (Redel-10 → Redel-10, yellow)		
length: 10 m	M490010	
length: 15 m	M490029	
length: 25 m	M490012	
length: 30 m	M490013	
Mains Cable, length: 3 m		
Australia	M4900601	
Brazil	M4900609	
China	M4900410	
EU	M4900108	
India / South Africa	M4900604	
Israel	M4900606	
Japan	M4900210	
Russia	M4900603	
Switzerland	M4900605	
Taiwan	M4900607	
UK / Singapore / Hong Kong	M4900602	
USA	M490024	

Item	Part #	
Serial Data Communication Cable for CARTO® Systems or Electrophysiology Recording Systems (Redel-9 → Dsub-9, gray)		
length: 3 m	M490021	
length: 5 m	M490025	
length: 15 m	M490023	

4.3 Caring for Accessories

WARNING
Do not modify any accessories.

4.3.1 Connection Cables

Visually inspect all connection cables before each use. Do not use damaged cables.

To avoid damage to the connection cables, do not wrap the cables around the remote control or other apparatus. Coiling the connection cables during normal operation of the remote control creates inductive components which can lead to interruption of the operation of the remote control.

When plugging in a cable or unplugging a cable, hold the cable by the plug housing, not by the cable itself.

4.3.2 Foot Pedal

Never pick up the foot pedal by its cable. Do not coil the cable closely around the foot pedal. Check the cable regularly for visible damage. Do not use a damaged foot pedal.

4.4 Cleaning, Disinfecting, and Sterilizing Accessories

To ensure that the accessories are safe to use, follow the cleaning, disinfecting, and sterilizing instructions in the instructions for use provided with the accessories. Make sure that any liquid is removed from electrical contacts after cleaning, disinfecting, or sterilizing.

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5 Remote Control Operation

The SmartAblate™ Remote Control is operated in the same manner as the SmartAblate™ RF Generator except as described below. See the SmartAblate™ RF Generator User Manual for instructions on features that the remote control shares with the generator.

5.1 Remote Control Startup

Quick Steps

- Connect the remote control to the mains supply and to the generator.
- Verify that the generator is on.
- Press the **Stand-by** button to turn on the remote control.
- At the message, press the **Stop** button on the front of the remote control.

Notes

1. When you press **Stand-by**, make sure that **Ablation Start** and **Stop** and the foot pedal are not pressed.
2. When you turn on the remote control, the remote control's audible and visual indicators are tested to allow you to verify that they are functional. The **Stand-by** indicator lights up and the SmartAblate™ System logo appears on the screen. The **Alarm** indicator flashes alternately red and orange for a short time to indicate that the **Alarm** indicator is working. Also, the **RF On** indicator flashes orange and an audible RF tone is played briefly. If the indicators listed above do not perform as described, there is a problem with the remote control and you should contact Customer Support.
3. Progress dots in the bottom left corner of the screen indicate that the system is performing a self test. When the self test is successfully completed, a confirmation message appears asking you to press the **Stop** button to continue. After you press the **Stop** button, the screen currently displayed on the SmartAblate™ RF Generator will be displayed on the remote control. (If the generator is not on, the System Control screen will be displayed on the remote control.) If the progress dots do not appear, or if the number of dots stops increasing and the logo remains on the screen, or if the confirmation message does not appear, there could be a problem (see Section 6.2, Other Troubleshooting).
4. Always wait until the automatic self test has been successfully completed and the remote control has been made the Master of the system (see Section 5.3, Assigning the System Master) before starting the first steps of the procedure on the patient (for example, before anesthesia or before creating percutaneous access). Also, if using accessories that connect to the remote control's serial data ports, verify that the connections to those systems are functional prior to starting the first steps of the procedure. Doing this helps to detect problems with the device before the patient is in a phase of the intervention in which interruption could lead to an increased risk to the patient's health. Also perform a visual inspection of the accessories (see Section 4.3, Caring for Accessories).

5.2 Remote Control Shutdown

Quick Steps

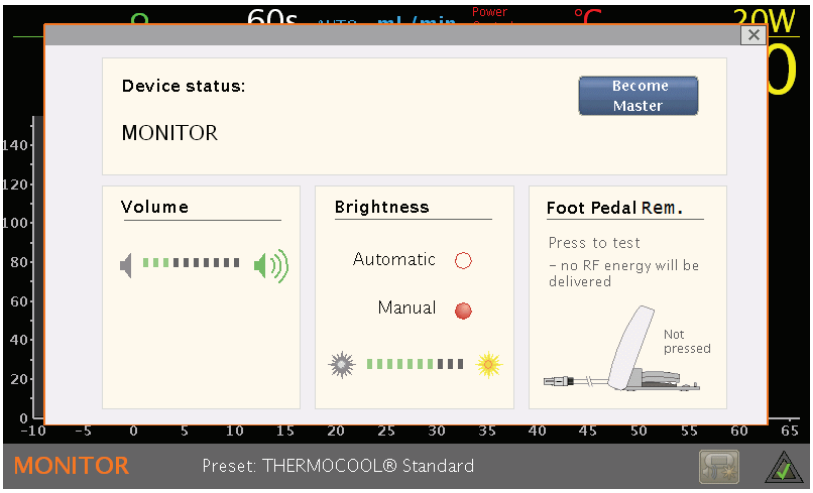
- Stop ablation.
- Press and hold the **Stand-by** button for approximately 3 seconds to turn off the remote control.

Note You can turn off the remote control before or after you turn off the generator.

5.3 Assigning the System Master

When you first turn on the remote control (see Section 5.1, Remote Control Startup), the word "MONITOR" is displayed at the bottom of the screen. This indicates that from the remote control, you can only observe system activities or stop ablation. When you want to control the system from the remote control, make the remote control the Master as described in this section.

System Control Screen (When Remote Control Is Monitor)



MONITOR

Quick Steps

- Press **System Control** on the Navigation Bar.
- Press **Become Master**.

Notes

1. Even when the remote control is the Monitor, you can stop ablation by pressing **Stop** on the remote control or by releasing the foot pedal.
2. If there is a problem with the connection to the generator, the System Control screen will display the message shown below. Follow the instructions in the message to resolve the problem. Also see Section 6.1, Problems with Connection to the Generator.

> **No connection detected to SMARTABLATE™ RF Generator**
>
> Check the following: the cable is free of cuts or kinks,
> the cable is properly connected and the SMARTABLATE™ RF Generator is on.
> The remote control software may be incompatible. Remote control SW Ver 1.0

5.4 Volume, Brightness, and Foot Pedal Test

Quick Steps

Press **System Control** on the Navigation Bar to open the System Control screen (see the image in Section 5.3, Assigning the System Master).

Volume

- Press the volume bar, then turn the **Data Entry Knob** to change the volume of the audio output.

Brightness

- Select **Automatic** to have the system determine the screen brightness.
- Select **Manual**, then press the brightness bar and turn the **Data Entry Knob** to adjust the screen brightness manually.

Foot Pedal

- Press the foot pedal connected to the remote control to verify that it is working. During the foot pedal test, a tone is emitted and the image changes to a pressed foot pedal. RF energy is not delivered during the foot pedal test (while the System Control screen is displayed).

Notes

1. When you press **System Control** on the remote control, the System Control screen appears only on the remote control (not on the generator). The volume and brightness changes that you make affect only the remote control and the foot pedal test applies only to the foot pedal connected to the remote control.
2. The volume setting affects the RF tone and all alarm and informational tones. Make sure that you select the appropriate volume so that you can hear the tones, or turn off the volume if you do not want to hear these tones on the remote control.
3. Take care when using the remote control and accessories. When the remote control is the system Monitor, ablation is automatically stopped when **Stop** is pressed or the foot pedal is released.

6 Troubleshooting

6.1 Problems with Connection to the Generator

If there is a problem with the connection between the SmartAblate™ Remote Control and the SmartAblate™ RF Generator, the System Control screen will appear with an explanatory message (see Section 5.3, Assigning the System Master).

Possible Reasons for Connection Problem	What To Do
The remote control is not connected to the generator.	Connect the remote control to the generator.
The generator is powered off.	Turn on the power to the generator.
There are communication problems between the generator and the remote control.	Replace the communication cable between the generator and the remote control.
The communication cable between the generator and the remote control is damaged.	Replace the communication cable between the generator and the remote control.
The generator had a fatal system error.	Follow the instructions in the SmartAblate™ RF Generator User Manual for troubleshooting a fatal system error.
The remote control has a software version that is not compatible with the generator's software version.	The software version on the remote control needs to be updated. Contact Customer Support.

6.2 Other Troubleshooting

Problem	What To Do
On startup, the progress dots do not appear or the logo screen does not disappear.	Press and hold **Stand-by** for approximately 3 seconds to turn off the remote control. Then press **Stand-by** again to turn the remote control on. If the problem persists, contact Customer Support.
On startup, after you press **Stop** in response to the message that appears, the screen currently displayed on the generator does not appear.	Unplug the foot pedal and plug it in again. Then press and hold **Stand-by** for approximately 3 seconds to turn off the remote control. Then press **Stand-by** again to turn the remote control on. If the problem persists, contact Customer Support.
Nothing happens when you press a button on the screen.	See Section 6.3, Calibrating the Touch Screen.
The remote control won't turn on.	Verify that the power supply meets the specifications in Section 7.1, Specifications. If the problem persists, contact Customer Support.

6.3 Calibrating the Touch Screen

Over time, the buttons on the touch screen may move a little and the location that you press on the screen may no longer be exactly where the button is. If this happens, follow the steps below.

Quick Steps

- Press the **CONNECTIONS** workflow button.
- Press **System Settings** .
- Press **Calibrate Touch Screen**.
- Press each target after it appears (a total of 6 targets).
- Press **Stop** .

Notes

1. You can only calibrate the remote control's screen when the remote control is the system Master (see Section 5.3, Assigning the System Master).
2. At any time during the calibration process, you can press **Stop** to exit calibration.
3. If the calibration is successful, you will see **Result:** . If the calibration is unsuccessful, you will see **Result:** . If the calibration is unsuccessful, repeat the steps until a successful calibration is achieved. If the problem persists, contact Customer Support.
4. When you perform calibration, be careful to press directly on the center of the target. If the calibration fails, try touching the center of the target with the tip of a pen instead of your finger.

7 Technical Data

7.1 Specifications

Mains

Voltage	100-240 V
Frequency	50/60 Hz
Power consumption	40 VA

Other

Classifications	Class I (as defined in IEC/EN 60601-1) Class IIb (as defined in MDD 93/42/EEC) Class 3, FDA There are no applied parts.
Weight	4.5 kg
Dimensions	395 mm wide x 220 mm high x 170 mm deep
IP rating	IP21

7.2 Storage and Shipping Conditions

Ambient temperature	-30° to +65°C
Relative humidity	10% to 90% (non-condensing)
Atmospheric pressure	500 to 1060 mbar

7.3 Operating Conditions

Ambient temperature	10° to 40°C
Relative humidity	10% to 85% (non-condensing)
Atmospheric pressure	700 to 1060 mbar

7.4 Safety Inspections

To ensure the safety of the SmartAblate™ Remote Control, inspect the remote control before each use. Perform the following verifications.

- Verify that all of the visual and audible indicators available on the remote control are functional (see Section 5.1, Remote Control Startup).
- Verify that the Data Entry Knob is not loose and that the values on the screen change as expected when the knob is turned.
- Verify that the foot pedal is not damaged and that it functions correctly (see Section 5.4, Volume, Brightness, and Foot Pedal Test).
- If using accessories that connect to the remote control, verify that the connections to those systems are functional.

Once a year, perform the verifications listed above as well as those below.

- The device label is present and readable.
- The cable connection receptacles are not damaged and are not loose.
- The accessory cables (especially the mains cable) are not damaged.
- The remote control can function as the system Master. (Make the remote control the system Master and then perform ablation using a STOCKERT test box for the SmartAblate™ RF Generator.)

Because the remote control is a medical device, some countries require an electrical safety test. If local regulations require a safety test, have the remote control tested by a technician certified by the local governing agency.

⚠ Important Notice

To ensure the safety of the SmartAblate™ Remote Control, repairs may be performed only by the manufacturer, a service engineer certified by the manufacturer, or a service center certified by the manufacturer. The safety inspections must be performed at least once a year, and after every repair, according to IEC/EN 60601-1 and its sub-standards and IEC/EN 62353.

7.5 Maintenance

Perform the safety inspections specified in Section 7.4, Safety Inspections.

Regularly clean and disinfect the SmartAblate™ Remote Control per Section 3.5, Cleaning and Disinfecting the Remote Control.

Regularly clean the accessories per the instructions for use provided with the accessories.

At least once a year, verify that the SmartAblate™ Remote Control and its accessories are installed per Section 3.4, Setup.

At least once a year perform the touch screen calibration per 6.3, Calibrating the Touch Screen.

At any time, if any problems are found, report them to Customer Support and send the remote control or broken accessory for repair.

If desired, a service contract can be arranged. Contact Customer Support.

7.6 Repairs

There are no parts in the SmartAblate™ Remote Control that may be serviced by the user. Repairs or any changes to the remote control and the accessories must be performed only by the manufacturer, a service engineer authorized by the manufacturer, or service centers certified by the manufacturer.

7.7 Conformance to Standards

The SmartAblate™ Remote Control meets the requirements of the following standards.

Standard	Title
ANSI / AAMI HF-18	Electrosurgical devices
CAN/CSA C22.2 No. 601.1, B-90	Medical electrical equipment - Part 1: General requirements for safety
CMDR	Canadian Medical Devices Regulations
DIN EN 980	Symbols for use in the labeling of medical devices
DIN EN 1041	Information supplied by the manufacturer of medical devices
DIN EN ISO 14971	Medical devices - Application of risk management to medical devices
EU Dir. 2002/96/EC	EU Directive 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment (WEEE)
IEC 60812	Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)
IEC/EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC/EN 60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC/EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC/EN 60601-1-4	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
IEC/EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC/EN 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC/EN 60601-1-9	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
IEC/EN 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC/EN 62304	Medical device software - Software life cycle processes
IEC/EN 62353	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
IEC/EN 62366	Medical devices - Application of usability engineering to medical devices

Standard	Title
MDD 93/42/EEC / MPG (Medical Products Law)	Medical Device Directive (MDD) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
UL 60601-1	Medical electrical equipment - Part 1: General requirements for safety

7.8 EMC Information and Technical Description

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables approved by the manufacturer of the SmartAblate™ Remote Control as replacement parts for internal components, may result in increased emissions or decreased immunity of the SmartAblate™ Remote Control.

Electromagnetic Emissions

The SmartAblate™ Remote Control is intended for use in the electromagnetic environment specified below. The customer or user of the SmartAblate™ Remote Control should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The SmartAblate™ Remote Control uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SmartAblate™ Remote Control is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The SmartAblate™ Remote Control is intended for use in the electromagnetic environment specified below. The customer or user of the SmartAblate™ Remote Control should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartAblate™ Remote Control requires continued operation during power mains interruptions, it is recommended that the SmartAblate™ Remote Control be powered from an uninterruptible power supply. Note that a 5 second removal of power, as tested, results in the device shutting down and requires user intervention to restart. There was no interruption of operation for other tests.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level. The SmartAblate™ Remote Control was tested at 100 and 230 VAC.

Electromagnetic Immunity

The SmartAblate™ Remote Control is intended for use in the electromagnetic environment specified below. The customer or user of the SmartAblate™ Remote Control should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the SmartAblate™ Remote Control, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17\sqrt{P}$ 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartAblate™ Remote Control is used exceeds the applicable RF compliance level above, the SmartAblate™ Remote Control should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SmartAblate™ Remote Control.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the SmartAblate™ Remote Control

The SmartAblate™ Remote Control is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the SmartAblate™ Remote Control can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartAblate™ Remote Control as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

EMC Information and Technical Description

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this user manual.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

⚠ Warning: The use of ACCESSORIES, transducers, and cables other than those specified, with the exception of transducers and cables approved by the manufacturer of the SmartAblate™ Remote Control as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the SmartAblate™ Remote Control.

⚠ Warning: Do not operate the remote control in the immediate vicinity of devices that are not approved for electromagnetic compatibility (EMC) with the remote control. If such operation is unavoidable, regularly monitor the remote control to ensure proper functioning.

⚠ Warning: The SmartAblate™ Remote Control may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

The SmartAblate™ Remote Control may be operated only with cables provided by or recommended by the manufacturer.

See Section 4.1, Diagram of the Remote Control and Accessories for an illustration of the typical configuration and the cables required for undisturbed operation.

8 Symbols

Symbol	Description
Distributed by	The device is distributed by
Manufactured by	The device is manufactured by
	Quantity
	Catalog number
	Alarm
	Rotational adjustment. Clockwise rotation increases value.
	Follow operating instructions.
	Follow operating instructions.
	Upper and lower temperature limits (storage and shipping conditions)
	Upper and lower humidity limitation (storage and shipping conditions)
	Upper and lower atmospheric pressure limitation (storage and shipping conditions)
	Keep dry
	Caution
	Radiofrequency
	Alternating current
	Serial data port
	USB port
	Generator receptacle
	Foot pedal receptacle
	Manufacturer
	Manufacturing date

Symbol	Description
SN	Serial number
LOT	Lot number
JP	Japanese version of the SmartAblate™ Remote Control
US	United States version of the SmartAblate™ Remote Control
WW	Worldwide version of the SmartAblate™ Remote Control (except the United States and Japan)
CLASSIFIED c UL us	Medical – General medical equipment as to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 / CAN/CSA C22.2 NO. 601-1 / ANSI/ AAMI ES60601-1 (2005) / CAN/CSA C22.2 NO. 60601-1 (2008) 40GF
CE 0366	CE marking with the number of the notified body
	Separate collection for electrical and electronic equipment
PHT	The device does not contain phthalates.
LATEX	The device is latex-free.
RoHS ✓	RoHS compliant (Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment)
	RoHS compliant (marking according to Chinese Administration on the Control of Pollution Caused by Electronic Information Product – ACPEIP - standard SJ 11364/2006)
IP21	The device is protected against solid foreign objects of 12.5 mm diameter and greater and is protected against vertically falling water drops.
Made in Germany	Certificate of origin in Germany
HW-Rev.	Hardware revision number
	Speaker receptacle

9 Warranty

9.1 Transit Damage

The SmartAblate™ Remote Control and accessories must be examined for transit damage immediately after receipt. If the remote control and accessories are damaged, notify Customer Support. Damage claims can be validated only if the seller or the shipping agent is informed immediately. For your convenience, an "Error Report" form is shipped with the remote control; you can use this form to record any damage.

9.2 Warranty

The warranty for the SmartAblate™ Remote Control warrants that the remote control will conform to its product specifications for a period of one year from the date of shipment or for the period of time defined in the purchase contract. The warranty does not cover normal wear and tear, damage due to improper handling, accessories, connection cables, and disposable parts. Repairs or any changes may be performed only by the manufacturer, a service engineer authorized by the manufacturer, or a service center authorized by the manufacturer. The warranty is voided if improper modifications or repairs are performed or if the device is not maintained according to the instructions in this user manual. The warranty is not extended or renewed by services performed under warranty.

9.3 Product Liability

Product liability is assumed by STOCKERT GmbH under the following conditions:

- The remote control has been operated only with the original accessories provided by or recommended by the manufacturer (see Chapter 4, Accessories).
- Repairs to the remote control and to the accessories have been performed only by the manufacturer, a service engineer authorized by the manufacturer, or by a service center authorized by the manufacturer.

Manufactured By

STOCKERT GmbH
Bötzinger Straße 72
79111 Freiburg, Germany
Fax: +49-761-20716-20
Email: info@stockert.de
http://www.stockert.de

Customer Support – In USA

Biosense Webster, Inc.
Tel: +1-866-4SERVCE (+1-866-473-7823) (toll free in USA)
Email: complaint@bwius.jnj.com

Customer Support – Outside USA

Biosense Webster
Tel: +32-2-7463-463
Email: techsupport@its.jnj.com

Distributed By

Outside USA
Biosense Webster
A Division of Johnson & Johnson Medical NV/SA
Leonardo da Vincilaan 15
1831 Diegem, Belgium
Tel: +32-2-7463-401
Fax: +32-2-7463-403

In USA
Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, California 91765 USA
Tel: +1-866-473-7823
Fax: +1-909-468-2786
http://www.biosensewebster.com

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

SMARTABLATE™ Remote Control
Firmware 1.XX.XX

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